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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/08/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/728,986	NILSSON ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-48,50-53,56,58-63,65-68 and 71-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-48,50-53,56,58-63,65-68 and 71-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 44-48, 50-53, 56, 58-63, 65-68, and 71-73 are pending. Applicants previously canceled claims 1-43. Applicants have newly cancelled claims 49, 54-55, 57, 64, and 69-70. Applicants have amended claims 44, 52-53, 56, 59, 67, and 71. Receipt and consideration of Applicants' new IDS (submitted on December 5, 2006), amended claims, and, arguments/remarks submitted on November 7, 2006 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 5, 2006 has been entered.

Moot Rejections/objections

All rejections and/or objections of claims 49, 54-55, 57, 64, and 69-70 cited in the previous office action mailed on August 7, 2006 **are moot**, because said claims have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 44-48, 50-53, 56, 58-63, 65-68, and 71-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44 and 59 are vague and indefinite because it is unclear what would constitute the "gradual aerosolization" of the dry powder dose during delivery. The specification does not define what is meant by "gradual aerosolization" of a dry powder. Therefore, an ordinary artisan would be unable to ascertain the metes and bounds of this limitation.

The remaining claims are rejected for depending upon a rejected claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 44, 45, 47-48, 50, 52-53, 56, 58-60, 62-63, 65, and 67-68, and 71-73 under 35 U.S.C. 102(b) as being anticipated by Davies (US 2002/0053344) **is maintained** for the reasons of record set forth in the office action mailed on March 27, 2006, further explained in the office action mailed on August 7, 2006, and further articulated herein below.

Response to Arguments

Applicant's arguments filed November 7, 2006 have been fully considered but they are not persuasive. Applicants traversal of the instant rejection is based on their assertions that (1)

the Davies reference is allegedly the basis for the commercially available dry powder inhaler known under the commercial trademark of DISKUS®, which according to several non-patent literature publications provided in the IDS submitted on December 5, 2006 is characterized by problems associated with the ingress of moisture due to the nature of the blister seals and (2) Davies lacks the disclosure of the gradual aerosolization of the dry powder dose during delivery. The Examiner respectfully disagrees with Applicants' traversal arguments. Regarding argument (2) this limitation is given little patentable weight because it is unclear from Applicants' disclosure, as set forth above in the instant office action in the rejection under 35 U.S.C. §112, 2nd paragraph, what constitutes gradual aerosolization of dry powder. Regarding Applicants' traversal argument (1), Applicants have provided no evidence that the medical product disclosed by the Davies reference is the same medical product known under the commercial trademark of DISKUS®. Therefore, because the Davies reference discloses a medical product comprising a hermetically sealed container comprising a seal foil containing tiotropium dry powder (i.e. dry moisture tight container containing tiotropium), it is the Examiner's position that said medical product inherently has all the properties associated with Applicants' claimed medical product because it has the same claimed components (e.g. moisture tight seal foil).

The rejection of claims 44-46, 50, 53, and 56 under 35 U.S.C. 102(e) as being anticipated by Goede et al. **is withdrawn** per Applicants' amendments requiring that the medical product comprise a seal foil.

Response to Arguments

Applicant's arguments, see page 12, filed November 7, 2006, with respect to the rejection of claims 44-46, 50, 53, and 56 under 35 U.S.C. 102(e) as being anticipated by Goede et al. have been fully considered and are persuasive. The rejection of claims 44-46, 50, 53, and 56 under 35 U.S.C. 102(e) as being anticipated by Goede et al has been withdrawn.

Claims 44-48, 50-53, 58-63, 65-68, and 72-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Pasbrig et al. (US 2006/0102511).

Applicants claim a medical product comprising a dry powder dose comprising at least one of tiotropium and physiologically acceptable salts thereof, wherein the medical product comprises a moisture-tight seal foil fixed to a dry moisture-tight container that prevents the ingress of moisture into the powder dose, and wherein the medical product is designed to provide gradual aerosolization of the dry powder dose during delivery.

NOTE: The limitation requiring that the dry powder be gradually aerosolized during delivery is given little patentable weight because it is unclear from Applicants' disclosure, as set forth above in the instant office action in the rejection under 35 U.S.C. §112, 2nd paragraph, what constitutes gradual aerosolization of dry powder. Limitations associated with the intended use of the claimed medical product are also given little patentable weight (e.g. delivered fine particle fraction).

Pasbrig discloses a blister package for inhalable medicaments comprising (a) a base sheet in which blisters are formed to define pockets therein for the containment of inhalable medicament; and (b) a lid sheet which is sealable to the base sheet except in the region of the

blisters and mechanically peelable from the base sheet to enable release of said inhalable medicament. The base sheet and/or said lid sheet have a laminate structure comprising (a) a **first layer of aluminum foil**; and (b) a second layer of polymeric material of thickness from 10 to 60 micron, said polymeric material having a water vapor permeability of less than 0.6 g/(100 inches^2) (24 hours) (mil) at 25 °C (title; abstract; [0012]; [0092]-[0094]; and claims 1, 6, 15). The medicament pack and related medicament dispense device of the invention is suitable for dispensing **medicament products, particularly for the treatment of respiratory diseases such as asthma, COPD, bronchitis, and chest infections** [0105].

Suitable medicaments include **anticholinergics, such as tiotropium, atropine, or oxitropium** ([0105], [0107], [0117], [0118], [0130]); **anti-inflammatory corticosteroids** ([0105], [0107], and [0108]-[0109]), NSAIDs (, [0107] and [0119]), **PDE4 inhibitors** ([0107] and [0110]-[0115]), **antihistamines** ([0107] and [0119]), **beta2-adrenoreceptor agonists** ([0105], [0107], and [0129]) and mixtures thereof ([0107]). Particularly suitable anticholinergics include **tiotropium bromide** [0118]. Suitable combinations include the co-formulation of a corticosteroid or beta-2 agonist, such as fluticasone propionate or salmeterol, respectively, in combination with a PDE4 inhibitor or an anticholinergic (e.g. **tiotropium bromide**) ([0130]).

Generally, the powdered medicaments suitable for delivery to the bronchial or alveolar region of the lung have an aerodynamic diameter below 10 microns, preferably below 6 microns. The powder medicament may be delivered in pure form, or preferably the medicaments are **delivered together with excipients (carriers)**, such as polysaccharides, lactose, glucose, mannitol, etc., wherein **lactose is a preferred excipient** ([0132]).

Regarding the claimed properties that original fine particle fraction is preserved for at least 7 or 14 days; the container does not emit water; and the delivered fine particle dose is at least 56% of the delivered dose, these are inherent to the medical product disclosed by Pasbrig, because it has the same components claimed by Applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 51 and 66 under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (US 2002/0053344) in view of Zierenberg, B. (WO 03/084502) **is maintained** for the reasons of record applied to claims 4, 15, 25, and 36 in the office action mailed on March 27, 2006, further explained in the office action mailed on August 7, 2006, and further articulated herein below.

Response to Arguments

Applicant's arguments filed November 7, 2006 have been fully considered but they are not persuasive. Applicants' traversal arguments of the instant rejection are the same as those applied to the rejection under 35 U.S.C. § 102(b) as being anticipated by Davies and found unpersuasive. The Examiner's position regarding these traversal arguments is the same here and are applied in full to the traversal of the instant rejection under 35 U.S.C. § 103(a). Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention and the instant rejection remains proper.

The rejection of claims 51, 58-61, 65, 66, 71, and 73 under 35 U.S.C. 103(a) as being unpatentable over Goede et al. in view of Keller **is withdrawn**, per Applicants' amendments requiring that the medical product comprise a seal foil.

Response to Arguments

Applicant's arguments, see page 12, filed November 7, 2006, with respect to the rejection of claims 51, 58-61, 65, 66, 71, and 73 under 35 U.S.C. 103(a) as being unpatentable over Goede et al. in view of Keller have been fully considered and are persuasive. The rejection of claims 51, 58-61, 65, 66, 71, and 73 under 35 U.S.C. 103(a) as being unpatentable over Goede et al. in view of Keller has been withdrawn.

Claims 56 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pasbrig et al. (US 2006/0102511) in view of Caper et al. (U.S. Patent No. 5,692,496) ("Casper").

Applicant Claims

Applicants claim a medical product as described above, wherein said product is a separate part adapted for insertion into a dry powder inhaler.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The disclosures of Pasbrig have been set forth above and additional relevant disclosures are set forth here. Pasbrig teaches that the use of medicament dispensers in the delivery of medicaments to the lung is well known and these dispensers generally comprise a body or housing within which a medicament carrier is located. **Known inhalation devices include those in which the medicament carrier is in blister pack form (e.g. an elongate blister strip) containing a number of discrete doses of powdered medicament**. In use, the blister pack is

typically housed within the dispenser in such a way that the blisters may be transported through the dispenser in indexed fashion to enable accessing of the discrete doses of medicament carried thereby. Such devices usually contain a mechanism of individually accessing the doses contained within the blisters. Known access mechanisms typically comprise either blister piercing means or means to peel a lid sheet away from a base sheet of the blister pack. The powdered medicament can then be accessed and inhaled.

Casper teaches there are essentially two classes of inhalation devices currently available in the marketplace for the administration of a powdered medicament to the lungs, pressurized metered dose inhalers and **dry powder inhalers (DPI)** (col. 1, lines 24-27 and 43-45). One method for delivering of dry powder medicaments with a DPI relies on providing a package containing multiple doses of medicament, each contained in a sealed blister. The package is used in conjunction with a specially designed inhalation device, which provides a means of attachment for the package and perforation of an individual blister, by the patient prior to the inhalation of its contents (col. 2, lines 10-17).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Pasbrig lacks the express teaching of a medical product that is a separate part adapted for insertion into a dry powder inhaler. This deficiency is obvious per the teachings of Pasbrig, as demonstrated by the teachings of Casper.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to an ordinary skilled artisan to use a medical product such as a blister pack that is adapted for insertion into a dry powder inhaler, which contains powdered medicaments intended for delivery by inhalation. The teachings of Pasbrig obviously imply that Pasbrig's invented blister pack is intended for use with an inhalation device. Casper's teachings demonstrate that conventional inhalation devices for the administration of a dry powder medicament without the use of a propellant are dry powder inhalers and that it is conventional to use blister packs designed as a separate part for insertion into a DPI. As a result, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention that Pasbrig's invented blister pack is adapted for use as a separate part for insertion into a dry powder inhaler, because DPI's are conventional devices for the delivery of powdered medicaments via inhalation and blisters are conventionally used as a separate package for insertion into a DPI. The teachings of Casper were provided to indicate what was conventional knowledge in the art at the time of the instant invention. Therefore, because Pasbrig's invented blister pack is intended to be used in association with a device to deliver powdered medicaments to the lungs (i.e. bronchi and/or alveoli) of a patient via inhalation, an ordinary skilled artisan would have had a reasonable expectation of successfully using the Pasbrig blister pack in this manner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections on the ground of nonstatutory obviousness-type double patenting cited on pages 10-17 of the office action mailed on 3/27/06 and maintained on pages 7-11 of the office action mailed on 8/7/06 (i.e. rejections over copending applications: 10/603,819; 10/703,505; 10/729,024; 10/834,037; 10/870,907; 10/870,909; 10/870,945; 10/921,192; and 10/933,219) **are maintained** for the reasons of record.

Response to Arguments

Applicant's arguments filed November 7, 2006 have been fully considered but they are not persuasive. Applicants' traversal arguments of the instant rejections are that the claims in the instant application can be passed to issue to first form a firm basis for comparison. This is found unpersuasive, because the instant claims are not in condition for allowance. The rejections will be maintained at this time.

Claims 44 and 59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52 and 67 of copending Application No. 11/448,773 (copending '773). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. The medial product of independent claim 44 has been described above. Dependent claim 52 of copending '773 discloses a medical product comprising a dry powder dose comprising at least one of tiotropium and physiologically acceptable slats thereof directly loaded into a container comprising a dry moisture-tight barrier seal that comprises formed or flat aluminum foils, optionally laminated with polymers. Independent claim 67 of the instant application is the same as independent claim 44, except that the medical product contains at least one additional active pharmaceutical ingredient. Dependent claim 67 of copending '773 is exactly the same as dependent claim 52, except that the medical product contains at least one additional active pharmaceutical ingredient selected from the same Markush group as those listed in claim 59 in the instant application. In conclusion, an ordinary skilled artisan at the time of the instant invention would have found claims 44 and 59 of the instant application prima facie obvious over dependent claims 52 and 67 of copending '773.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 44-48, 50-53, 56, 58-63, 65-68, and 71-73 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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